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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,776

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David K. Boehm

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/757,776	Applicant(s) BOEHM ET AL.	
	Examiner DIANNE DORNBUSCH	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
4a) Of the above claim(s) 24-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/15/2004, 7/19/2004, 6/28/2005, 8/22/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-23, drawn to lancing device, classified in class 606, subclass 182.
 - II. Claims 24-31, drawn to a method of assembling the adjustable nozzle, classified in class 128, subclass 898.
 - II. Claims 32-37, drawn to a method of adjusting a lancing depth, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make another and materially different product such as the nozzle of a mechanical pencil that is rotated to adjust the amount of led that is sticking out of the device.
3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process

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for using the product as claimed can be practiced with another materially different product such as in any device that has a adjustable nozzle (i.e. a mechanical pencil) that rotates in order for the internal component (i.e. the led) to come out of the nozzle slowly and to the desired length.

4. Inventions II and III are directed to related distinct processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct since invention II is a process of manufacturing the nozzle while invention III is a process of using the nozzle. The invention I can have a different process such as using adhesives or welding to assemble the components of the nozzle which could have a final product that does not rotate therefore the depth of the nozzle cannot be adjusted. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Eric Raciti on February 2, 2008 a provisional election was made without traverse to prosecute the invention of I, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-37 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 5-7, and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Morita (5,730,753).

Morita discloses the following claimed limitations:

Claim 1: An adjustable nozzle assembly (1) through which a lancet can be propelled by a lancing device into a lancing surface, the adjustable nozzle assembly (1) comprising: an interior nozzle (3 specifically the top part 11) comprising a ramped groove (47) and a lancet wall (13); a collar (5) comprising a collar pin (53) that engages the ramped groove (47) and slides relative to the ramped groove (Col. 12 Lines 65-68 and Col. 13 Lines 9-14), the collar (5) being adapted to rotate relative to the interior nozzle (3,11) (Col. 12 Lines 12-15); and an exterior nozzle (7) comprising a contact surface (35) that extends beyond the lancet wall (13) of the interior nozzle (3,11) to contact the lancing surface (Fig. 1), the exterior nozzle (7) engaging the collar (5) (Col. 13 Lines 50-53) and being adapted to rotate relative to the interior nozzle (3,11) (Col. 13 Lines 58-60); and wherein the ramped groove (47) is sloped (Fig. 1) such that as the exterior nozzle (7) rotates relative to the interior nozzle (3, 11), the distance that the contact surface (35) extends beyond the lancet wall (13) changes by an amount that corresponds to the slope of the ramped groove (Col. 14 Lines 1-9).

Claim 3: That the collar (5) further comprises a sloped collar ramp (the collar ramp at the portion that contains the pin 53), the sloped collar ramp comprising a detent (the ramp of the detents between pin 53); and the interior nozzle (3,11) further comprises a

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sloped interior nozzle ramp (17), the sloped interior nozzle ramp (17) comprising a plurality of adjustment notches (the notches sticking out between the groove 47 where each time the circumference is completed a new notch is found) that can engage the detent (Fig. 2); and wherein the slope of the collar ramp, the slope of the interior nozzle ramp, and the slope of the ramped groove are approximately equal (Fig. 2 and Col. 13 Lines 5-8).

Claim 5: That the detent (the ramp of the detents between pin 53) forms a slotted portion (Fig. 3 where the detents are in the central portion of the collar) of the collar ramp (the collar ramp at the portion that contains the pin 53).

Claim 6: That the interior nozzle (3, 11) further comprises an assembly groove (39), one end of the assembly groove (39) being in proximity to one end of the ramped groove (47) (Fig. 1), the assembly groove (47) comprising a raised boss (37) that can oppose the collar pin sliding from the ramped groove to the assembly groove (Col. 11 Lines 66-67 and Col. 12 Lines 1-5).

Claim 7: That the collar (5) further comprises one or more collar alignment features (29, 25), and the exterior nozzle (7) further comprises one or more exterior nozzle alignment features (65, 55) that can engage the one or more collar alignment features (Col. 13 Lines 45-49 and Col. 14 Lines 28-30).

Claim 9: That the ramped groove (47) comprises an over-rotation groove. The ramped groove (47) has ends which are thinner which would not allow the collar (5) to rotate more than that point. Furthermore, the interior nozzle has a stopper (43) which will stop

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the device one component (25) of the collar (5) hit it. This is a prevention to over-rotation in addition to the end of the groove (47).

10. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofert et al. (4,203,446).

Hofert discloses the following claim limitations:

Claim 10: A rearward body assembly of a lancing device that can propel a lancet (12) into a lancing surface, the rearward body assembly comprising: a lancet holder (16) comprising one or more retaining features (14) and one or more spring surfaces (the outer area and the top surfaces of the lancet holder are spring surfaces since the surface is in contact with the springs); an interior tube (34) comprising an open end (proximal end as seen in the Figure) and a slotted end (distal end where it is stepped as seen in the Figure) through which the one or more retaining features (14) extend (see the Figure), the interior tube (34) being adapted to slidably engage the lancet holder (16) (the lancet holder is placed inside the inner tube as seen in the Figure); an internal compression spring (36) comprising a first end and a second end (see Figure), the first end of the internal compression spring (36) being adapted to act on the slotted end of the interior tube (34) (the proximal end of the spring is in contact with the slotted area as seen in the Figure) and the second end of the internal compression spring (36) being adapted to act on the one or more spring surfaces of the lancet holder (16) (the distal end is in contact with the lancet holder so when a force is applied on the spring it will act on the spring surfaces); a retainer (14) comprising a slotted surface (it has a slot in the center where the lancet is slid through) through which the one or more retaining

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features extend (the retaining features of 14 are internal where the lancet is mounted to) (Col. 2 Lines 52-53); a rearward body (combination of 24 and 22), the rearward body engaging the retainer (14) (when the rearward body is displaced in the forward direction it will engage with the retainer); and an external compression spring (20) comprising a first end and a second end (see the Figure), the first end comprising a reduced coil diameter that engages the one or more retaining features (14) of the lancet holder (16) as seen in the Figure, the first end of the external compression spring being adapted to act on the lancet holder (the spring is holding the lancet holder which will act on it to cause the deployment of the lancet) and the second end of the external compression spring being adapted to act on the slotted surface of the retainer (the spring is compressing on the retainer therefore it is acting on the slotted surface); and wherein longitudinal movement of the rearward body away from the interior tube compresses the interior compression spring (Col. 3 Lines 5-10).

Claim 11: That the lancet holder (16) further comprises a trigger extension (22), the trigger extension being adapted to engage both a trigger and the interior tube to load the lancing device and to oppose the force of the compression spring until the trigger is actuated. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim 12: That the retainer (14) further comprises one or more retainer alignment features (the step portion and the end of the lancet holder (16) serve as alignment features that maintain the retainer centered), and the rearward body (combination of 24

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and 22) further comprises one or more rearward body alignment features (the piece 24 serves as an alignment feature which has to fit on the center of the lancet holder (16) which has the retainer (14)) that can engage the one or more retainer alignment features. The rearward body engages to the step portions of the retainer which maintains the rearward body centered.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753).

Morita discloses that the collar (5) further comprises a plurality of adjustment notches (51, 57) and wherein the interior nozzle (3, 11) further comprises a cantilevered detent (39, 41) that can engage the cantilevered detent (Fig. 2).

Morita discloses the claimed invention except for the location of the notches and the detents, where the notches are in the collar and not in the interior nozzle and the detents are in the interior nozzle not on the collar. It would have been obvious to one having ordinary skill in the art at the time the invention was made have the notches on the interior nozzle and the recess on the collar, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753) in view of Bajaj et al. (6,056,765).

Morita discloses all the claimed limitations discussed above however, Morita does not disclose that the detent forms a cantilevered portion of the collar ramp.

Bajaj discloses that the detent (136 shown in Fig. 1 on component 104) forms a cantilevered portion of the collar ramp (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Morita with detent that forms a cantilever in view of the teachings of Bajaj, in order to provide a flexible portion of the collar that can store the energy and serve as a cushion when the device is place on the lancet surface and ejected.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753) in view of Duchon et al. (5,964,718).

Morita discloses all the claimed limitations discussed above however, Morita does not disclose that the contact surface is concave.

Duchon discloses that the contact surface (48) is concave (Col. 5 Lines 28-30 and Fig. 13)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Morita with a concave contact surface in view of the teachings of Duchon, in order to have a contact surface that adjusts to the lancing surface with minimal impact on the lancing surface.

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15. Claim 13, 15, 17-19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753).

Hofert teaches all the claimed limitations discussed above (see 102(b) rejections of claims 10-12 which reads on the rearward assembly of claim 13, 22, and 23) however, Hofert does not disclose an adjustable nozzle assembly.

Morita discloses all the features of the adjustable nozzle claimed in claims 15, 17-19, and 21 (refer to 102(b) rejections of claims 1, 3, 5-7, and 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert with an adjustable nozzle in view of the teachings of Morita, in order to adjust the puncturing depth of the lancet on the tissue which will adapt to different skin thickness or change the amount of blood that needs to be collected.

16. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753).

Morita discloses that the collar (5) further comprises a plurality of adjustment notches (51, 57) and wherein the interior nozzle (3, 11) further comprises a cantilevered detent (39, 41) that can engage the cantilevered detent (Fig. 2).

Therefore Hofert in view of Morita discloses the claimed invention except for the location of the notches and the detents, where the notches are in the collar and not in the interior nozzle and the detents are in the interior nozzle not on the collar. It would have been obvious to one having ordinary skill in the art at the time the invention was made have the notches on the interior nozzle and the recess on the collar, since it has

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been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

17. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753) and further in view of Bajaj et al. (6,056,765).

Hofert in view of Morita discloses all the claimed limitations discussed above however, Hofert in view of Morita does not disclose that the detent forms a cantilevered portion of the collar ramp.

Bajaj discloses that the detent (136 shown in Fig. 1 on component 104) forms a cantilevered portion of the collar ramp (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert in view of Morita with detent that forms a cantilever in view of the teachings of Bajaj, in order to provide a flexible portion of the collar that can store the energy and serve as a cushion when the device is place on the lancet surface and ejected.

18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753) and further in view of Duchon et al. (5,964,718).

Hofert in view of Morita discloses all the claimed limitations discussed above however, Hofert in view of Morita does not disclose that the contact surface is concave.

Duchon discloses that the contact surface (48) is concave (Col. 5 Lines 28-30 and Fig. 13)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert in view of Morita with a concave contact surface in view of the teachings of Duchon, in order to have a contact surface that adjusts to the lancing surface with minimal impact on the lancing surface.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patents Levin et al. (Re 32,922) and Harding (5,613,978) all disclose a lancet device, where Harding discloses an adjustable nozzle that can be placed in the lancet device of Levin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/ (Jackie) Tan-Uyen T. Ho/
SPE of Art Unit 3773